Changes to legislation: *There are outstanding changes not yet made to Commission Regulation (EU) 2016/1381. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

Commission Regulation (EU) 2016/1381 of 16 August 2016 refusing to authorise a health claim made on foods and referring to children's development and health (Text with EEA relevance)

COMMISSION REGULATION (EU) 2016/1381

of 16 August 2016

refusing to authorise a health claim made on foods and referring to children's development and health

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods[(1)], and in particular Article 17(3) thereof,

Whereas:

(1) Pursuant to Regulation (EC) No 1924/2006 health claims made on foods are prohibited unless they are authorised by the Commission in accordance with that Regulation and included in a list of permitted claims.

(2) Regulation (EC) No 1924/2006 also provides that applications for authorisations of health claims may be submitted by food business operators to the national competent authority of a Member State. The national competent authority is to forward valid applications to the European Food Safety Authority (EFSA), hereinafter referred to as 'the Authority'.

(3) Following receipt of an application the Authority is to inform without delay the other Member States and the Commission thereof, and to deliver an opinion on the health claim concerned.

(4) The Commission is to decide on the authorisation of health claims taking into account the opinion delivered by the Authority.

(5) Following an application from Cross Vetpharm Group UK Ltd, submitted pursuant to Article 14(1)(b) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to β-galactosidase from *Kluyveromyces lactis* in Colief® and a reduction of gastrointestinal discomfort (Question No EFSA-Q-2014-00404[(2)]). The claim proposed by the applicant was worded as follows: 'Colief®/lactase enzyme reduces the lactose load of the infant's feed and improves the consequences of lactose maldigestion in colicky infants unable to effectively digest all the lactose in their feed'.

Changes to legislation: *There are outstanding changes not yet made to Commission Regulation (EU) 2016/1381. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

(6) On 17 July 2015, the Commission and the Member States received the scientific opinion from the Authority, which concluded that the evidence provided is insufficient to establish a cause and effect relationship between the consumption of β-galactosidase from *Kluyveromyces lactis* in Colief® and a reduction of gastrointestinal discomfort. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.

(7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

The health claim listed in the Annex to this Regulation shall not be included in the Union list of permitted claims as provided for in Article 14(1) of Regulation (EC) No 1924/2006.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 16 August 2016.

For the Commission

The President

Jean-Claude JUNCKER